

**Notice of Allowability**

Application No.

10/621,272

Examiner

Satyanarayana R. Gudibande

Applicant(s)

POTTERAT ET AL.

Art Unit

1654

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_.
2. ☒ The allowed claim(s) is/are 18-24.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 02/07/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the cancellation of claims 1-16, withdrawal of claim 17 and addition of claims 18-23 in an amendment filed on November 14, 2005.

### ***Allowable Subject Matter***

The following is an examiner's statement of reasons for allowance: Examiner searched SEQ. ID No. 1 and found it to be free of art. Claims 17-23, drawn to SEQ. ID No. 1 contain allowable subject matter.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 18-23 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claim 17, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, is now subject to being rejoined. Claim 17 is hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office action mailed on August 11, 2005 is hereby withdrawn.

Claim 17 has been canceled and renumbered and rewritten for clarity as new claim 24.

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**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. David Dow, Attorney for Applicant(s), Reg. No. 46,124 on December 19, 2005.

The claims have been amended as follows,

18. (**Currently amended New**) An A isolated or synthesized ~~purified~~ bicyclic oligopeptide

[-----]

HN-Gly<sup>1</sup>-Leu-Pro-Trp-Gly-Cys<sup>6</sup>-Pro-Ser-Asp<sup>9</sup>-Ile-Pro-Gly-

-Trp-Asn-Thr-Pro-Trp-Ala-Cys<sup>19</sup>-COOR,

comprised of (SEQ ID NO. 1):

wherein

the amino group of Gly<sup>1</sup> is linked with the  $\beta$ -carboxylate group of Asp<sup>9</sup> via an amide group, and the ~~thiol thiole~~ groups of the cysteines Cys<sup>6</sup> and Cys<sup>19</sup> are linked via a disulfide bridge and R is a H atom or a methyl group; or an ester thereof.

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19. (New) A medicament comprised of a bicyclic oligopeptide according to claim 18.
20. A Pharmaceutical composition comprising a bicyclic oligopeptide according to claim 18 and a pharmacologically acceptable carrier.
21. A pharmaceutical composition according to claim 20 further comprised of an active ingredient selected from the group consisting of antidiabetic agents, lipid modulating agents, anti-obesity agents and cardiovascular agents.
22. A pharmaceutical composition according to claim 21, wherein the antidiabetic agent is selected from the group **consisting of** ~~comprising~~ biguanides, glucosidase inhibitors, PPARgamma modulators, dual PPARalpha/gamma agonists, RXR modulators, SGLT2 inhibitors, aP2 inhibitors, insulin sensitizers, GLP-I or mimetics, DPPIV inhibitors, PTP-IB inhibitors, GSK-3 inhibitors and a metiglinide.
23. A Pharmaceutical composition according to claim 21 ~~22~~ wherein the antidiabetic agent is selected from the group consisting of metformin, glyburide, glibenclamide, glimepiride, glypiride, glipizide, chlopropamide, gliclazide, acarbose, miglitol, pioglitazone, troglitazone, rosiglitazone, insulin, isaglitazone, repaglinide, nateglinide, and exendin-4.
24. (Currently amended) A method of treating diabetes mellitus **comprising** ~~comprised of~~ the ~~step~~ steps of administering to a patient in need thereof a therapeutically effective amount of a bicyclic oligopeptide according to **claim 18** ~~claim 1~~.

### *Conclusion*

Claims 18-24 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8 AM-4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyanarayana R. Gudibande, Ph.D.  
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A handwritten signature in black ink, appearing to read "Bruce Campell", written in a cursive style.

**BRUCE R. CAMPELL, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**